Art Unit: 1641

Reply to Office Action of 06/24/2009

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-26 Canceled

 (Currently Amended) A system for detecting glycated albumin in a sample and determining the percent glycated albumin comprising:

a solid support comprising a lateral flow membrane;

a single application pad containing a sample well disposed on said solid support, wherein said application pad comprises a porous material to retain red blood cells from said sample in said application pad;

a first assay comprising a first test strip that measures glycated albumin in said sample wherein said first test strip comprises sequential bands wherein one of said bands is a first control band:

a second assay comprising a second test strip that measures total albumin in the same sample as said first assay wherein said test strip comprises sequential bands wherein one of said bands is a second control band; and

means for calculating percent glycated albumin,

wherein said first test strip <u>has disposed therein microparticles which</u> specifically bind glycated albumin in said sample and said second test strip have <u>has</u> disposed therein microparticles which specifically bind glycated albumin or total albumin in said sample.

- 28. (Cancelled)
- 29. (Cancelled)
- (Previously Presented) The system of claim 27 wherein said system is an immunochromatographic system.
 - (Previously Presented) The system of claim 27 wherein said means for calculating percent glycated albumin comprises a

Art Unit: 1641

Reply to Office Action of 06/24/2009

measurement device that reads, calculates and displays the result as the percentage of glycated albumin compared to total albumin in the sample.

32. (Previously Presented) The system of claim 27, wherein said first test strip has disposed therein bands comprising:

a first conjugate band comprising microparticles coated with a first antibody to glycated albumin,

a first test band comprising a glycated albumin-specific immobilization agent covalently bound to said first test strip; and

a first control band.

- 33. (Previously Presented) The system of claim 32 wherein said immobilization agent is an antibody to glycated albumin.
- 34. (Previously Presented) The system of claim 32 wherein said microparticles are selected from the group consisting of colloidal gold particles, latex particles, polystyrene particles, acrylic particles or other solid phase microparticles.
- 35. (Previously Presented) The system of claim 27 wherein said second test strip has disposed therein bands comprising:

a second conjugate band comprising microparticles coated with a first antibody to albumin.

a second test band comprising a second antibody to albumin covalently bound to said second test strip; and

a second control band.

- 36. (Previously Presented) The system of claim 35 wherein said microparticles are selected from the group consisting of colloidal gold particles, latex particles, polystyrene particles, acrylic particles or other solid phase microparticles.
- 37. (Previously Presented) The system of either of claims 34 or 36, wherein said microparticles are colored or tagged with a fluorescent compound.
- 38. (Previously Presented) The system of claim 27 wherein the first test strip and the second test strip are arranged in a configuration selected from the group

Reply to Office Action of 06/24/2009

consisting of parallel, opposite to each other, and at an angle to each other.

39. (Previously Presented) The system of claim 27 wherein the first test strip and the second test strip are enclosed in a rigid cassette.

(Previously Presented) The system of claim 31 wherein said
measurement device is a reflectance spectrometer or a fluorometer comprising:

- a detector for measuring the glycated albumin test result;
- a detector for measuring the glycated albumin control band;
- a detector for measuring the total albumin test result;
- a detector for measuring the total albumin control band:
- an internal computer chip for measurement and calculation;
- a liquid crystal display;

an external port to transfer data to an external computer and/or printer;

- a battery and/or an external power source; and
- a rigid external case with an aperture for inserting the test cassette.
- 41. (Previously Presented) The system of claim 40 whereby the one or more than one test result can by displayed on said measurement device's liquid crystal display in numerical format or in graphical format.
- 42. (Previously Presented) The system of claim 40 further comprising an internal memory chip capable of storing one or more than one test result.
- 43. (Previously Presented) The system of claim 42 whereby the one or more than one test result can be transferred to an external computer or printer.
- (Currently Amended) A method of monitoring glycated albumin using a point-of-care assay and determining a percent glycated albumin level comprising:

depositing a drop of blood into a single sample well of an immunochromatography system test cassette according to claim 27:

transferring said blood into the sample application pad thereby allowing blood plasma to pass into a first conjugate band of a first test strip and into a second conjugate band of a second test strip;

Reply to Office Action of 06/24/2009

binding glycated albumin in said blood plasma to anti-glycated albumin antibody-coated microparticles in said first conjugate band:

binding albumin in said blood plasma to anti-total albumin antibodycoated microparticles in said second first conjugate band:

allowing glycated albumin and albumin bound antibody-coated microparticles in each of said first test strip and said second test strip to individually migrate across said conjugate bands to fixed bands of membrane-bound antibody;

binding said glycated albumin and albumin-bound antibody-coated microparticles in each of said first test strip and said second test strip to said membrane-bound antibodies to form colored or fluorescent bands;

allowing unbound antibody-coated microparticles to pass into a first control band in said first test strip and into a second control band in said second test strip:

inserting said immunochromatography system test cassette into a measurement device;

providing numerical results of glycated albumin levels from said first test strip and total albumin levels from said second test strip; and calculating said percent glycated albumin.